VIA ELECTRONIC FILING **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent Application of Hugh Semple Munro *et al.*	:	Attorney Docket No.: **101713-5026**
Appln. No.:	**10/538,427**	:	Examiner: Brandon Lee Jackson
Filed:	April 4, 2006	:	Confirmation No.: 3197
For:	ABSORBENT MULTILAYER HYDROGEL WOUND DRESSING	:	Group Art Unit: 3772

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of Patrick Trotter Pursuant to 37 C.F.R. § 1.132

I hereby declare as follows:

1. I, Dr. Patrick Trotter, founded and currently run the company InnProMa, a technical, innovation, project management and commercialization service. My educational background includes a Doctorate of Philosophy in Biochemistry and Molecular Biology from University of Leeds, and a Bachelor of Science degree in Biochemistry and Molecular Biology from University of Dundee. My professional experience includes seventeen years as a scientist, including five years in academia and twelve years in the medical device industry. During my career as a scientist, I have been an inventor on numerous patents.

2. I am familiar with U.S. Patent Application No. 10/538,427 (the '427 Application), including the subject matter of the patent application.

3. I am not being compensated in any way for the present Declaration.

4. I have read the Office Action dated May 13, 2009, in which the Examiner has rejected pending claims 1-20. I understand that the claims were rejected by the Examiner under 35 U.S.C. § 102(b), as allegedly being anticipated by Webster (U.S. Pat.

No. 4,541,426, hereinafter "Webster"), claims 2 and 20 rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Webster, claim 3 rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Webster in view of Takahashi et al. (U.S. Pat. No. 5,972,452), claims 6-12 rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Webster in view of Nielsen (U.S. Published Appln. No. 2003/0153860), and claims 16-17 rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Webster in view of Gilman et al (U.S. Pat. No. 5,811,116).

5. I have read U.S. Patent No. 4,541,426.

6. As set forth below, the pending claims in U.S. Patent Application No. 10/538,427 encompass wound dressings that are not disclosed, described, or suggested in U.S. Patent No. 4,541,426.

7. Prior to the time of filing of the present patent application, it is my opinion that those of skill in the relevant art understood the nature of hydrophilic dressings in contrast to hydrophobic dressings, and that those of skill in the relevant art understood the nature of cellular structures in contrast to continuous structures, as well as substantially continuous structures.

8. Webster describes the second portion as a "second layer compromising a material that does not swell or swells less than said first layer" (column 2, line 5-6; Webster). In the context of the preceding sentence, this second layer is clearly distinct from the first layer and the statement that it "does not swell or swells less than the first layer" clearly suggests 1) that it a material distinct from the first layer, and 2) that it is intended to be hydrophobic, in nature, compared to the first layer.

9. The Office Action states that the skin contacting layer "may be made of the same material, just a different absorbency". In terms of materials science this statement is not consistent. The fact that the material properties of the second layer are different than that of the first layer can only be interpreted as meaning that the material making up the second layer is 'different' than the material making up the first layer.

10. It is important to clarify that water absorbency is related to the ability of a material to absorb and retain water. The extent to which a material is absorbent is directly related to whether the material is hydrophobic or hydrophilic, with a hydrophobic material being essentially non-absorbent.

11. The physical properties of any material (including its absorbency) are dependent on the chemical composition and the physical structure of the material. If two materials were "the same", both would be expected to have identical swelling properties. If a material were to be chemically modified by adding more charged groups to the material, such as hydroxide groups, the resultant material would be expected to have a greater ability to form hydrogen bonds with water and therefore have more absorbency (i.e., a greater ability to bind water). Conversely, if more organic groups were chemically added to a material, the resulting material would have a reduced ability to bind water, and therefore, a reduced absorbency. In summary, the only way of changing the absorbency of a material is to change the structure at the molecular level.

12. Because the two layers in the Webster patent have different physical properties, they cannot be the same material. If, as described in Webster, the second layer has a lower ability to swell than the first layer, it must be substantially different at the molecular level. Webster describes the second layer as follows: "When in contact with water, it does not swell or swells less than the first layer." The second layer described by Webster must therefore be considered more hydrophobic than the first layer.

13. The Office Action states that "Webster discloses both layers may be polyamide or polyurethane" (cols 2-3, lines 29-1; col 4, lines 47-59). However, by using polyurethane as an example, what the Webster patent actually communicates can be clarified. Firstly, by way of background, not all polyurethanes are the same. Polyurethanes can be hydrophilic, hydrophobic, soft or very hard and brittle. The term polyurethane on its own cannot be used to fully describe a material. In Webster, with regard to layer one, it is stated that suitable polymers might be hydrophilic polyurethanes (col 2, line 57-58). In contrast, in reference to the nature of the polyurethane in the second layer, Webster recommends that Estanes™ are suitable. The structure of an Estane™ monomer is given

in Exhibit A, attached. The skilled artisan would conclude that Estane™ is hydrophobic in nature, and has a very low ability to bind water. This is in contrast to the example of the hydrophilic polyurethane Webster suggests as suitable for the first portion (e.g., Pebax4011 RN00, which has a water content of 55% when hydrated).

14. Other polymers recommended in Webster as being suitable for the second layer include polyethylene, polyisobutadiene and neoprene. The structure of the monomer part of the repeating unit for each of these is shown in Exhibit B. Again, one skilled in the art would interpret these structures as hydrophobic in nature and would predict materials composed of such polymers would have a low capability to bind water and therefore, a low absorbent capacity. Additional compounds proposed in Webster as suitable second-layer materials include Styrene-butadiene (e.g. Kraton™) and polyether polyesters (e.g. Hytrel™), both of which are also hydrophobic in nature. Only hydrophobic materials are exemplified as suitable for use in the second portion of the invention as described in the Webster patent.

15. Regarding the terms "cellular" and "substantially continuous", as used in the present patent application, these terms are art-accepted terms that can be used to describe the amount of closed compartments within a structure. For example, these terms can be used to describe opposite ends of a spectrum. A cellular structure is one in which the structure is divided into closed cells or compartments that have physical walls between them. In fact, the term "cellular" is an analogy to the appearance of biological cells that are encapsulated or surrounded by a membrane. The term cellular can be used to describe the structure, at a micro or macro level, of materials that have a similar visual appearance to that of cells. In a cellular structure the compartments are physically separated from adjacent cells, or compartments, by walls (see exhibit C).

16. In contrast, in a substantially continuous material, the cells are not closed but are open, and the intra-special void is typically not surrounded by walls on all sides (see Exhibit C). In practical terms, a continuous structure makes a material more porous and allows fluid to pass more readily than in a cellular structure. The water uptake rates in the two portions can be controlled by modifying the cellular density of the material. The

continuous structure as set forth in the present patent application is distinct from the cellular structures described in the Webster patent.

17. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 11th November 2009 Patrick Trotter

Patrick Trotter PhD MBA (TechMgmt)

EXHIBIT A

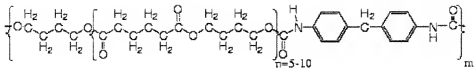
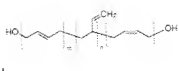


EXHIBIT B

a

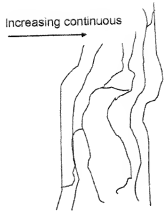


b

c

EXHIBIT C

Cellular structure



Substantially continuous structure